DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2015

Mölnlycke Health Care US, LLC
Ms. Megan Bevill
Regulatory Affairs Manager
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092

Re: K140477
Trade/Device Name: Biogel® PI Ultra Touch™ G Surgical Glove tested for use with chemotherapy agents, Biogel® SkinSense® Surgical Glove tested for use with chemotherapy agents
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's glove
Regulatory Class: I
Product Code: KGO, LZC
Dated: February 18, 2015
Received: February 20, 2015

Dear Ms. Bevill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140477

Device Name
Biogel® Skinsense® Surgical Glove tested for use with chemotherapy agents

Indications for Use *(Describe)*
Biogel® Skinsense® Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material, and other contaminants.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Biogel® Skinsense®	
Drug and Concentration	Breakthrough Detection Time in Minutes (0.01 µg/cm^2/ minutes)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	60.2
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
Ellence 2 mg/ml	>240
Etoposide (Toposar) 20 mg/ml	>240
Fludarabine 25 mg/ml	>240
Fluorouracil 50 mg/ml	>240
Idarubicin 1 mg/ml	>240
Ifosfamide 50 mg/ml	>240
Mechlorethamine HCl 1 mg/ml	>240
Melphalan 5 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2 mg/ml	>240
Paclitaxel (Taxol) 6 mg/ml	>240
Paraplatin 10 mg/ml	>240
Rituximab 10 mg/ml	>240
Thiotepa 10 mg/ml	75.8
Trisenox 0.1 mg/ml	>240
Vincristine Sulfate 1 mg/ml	>240

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compare to other chemotherapy drugs:

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 60.2 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 75.8 minutes.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140477

Device Name
Biogel® PI UltraTouch™ G Surgical Glove tested for use with chemotherapy agents

Indications for Use *(Describe)*
Biogel® PI UltraTouch™ G Surgical Gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infectious material, and other contaminants.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRAStaff@fda.hhs.gov

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Biogel® PI UltraTouch™ G	
Drug and Concentration	Breakthrough Detection Time in Minutes (0.01 μg/cm^2/ minutes)
Bleomycin 15 mg/ml	>240
Busulfan 6 mg/ml	>240
Carmustine 3.3 mg/ml	12.1
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10 mg/ml	>240
Doxorubicin Hydrochloride 2 mg/ml	>240
Ellence 2 mg/ml	>240
Etoposide (Toposar) 20 mg/ml	>240
Fludarabine 25 mg/ml	>240
Fluorouracil 50 mg/ml	>240
Idarubicin 1 mg/ml	>240
Ifosfamide 50 mg/ml	>240
Mechlorethamine HCl 1 mg/ml	>240
Melphalan 5 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2 mg/ml	>240
Paclitaxel (Taxol) 6 mg/ml	>240
Paraplatin 10 mg/ml	>240
Rituximab 10 mg/ml	>240
Thiotepa 10 mg/ml	15.5
Trisenox 0.1 mg/ml	>240
Vincristine Sulfate 1 mg/ml	>240

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compare to other chemotherapy drugs:

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 12.1 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 15.5 minutes

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared:	March 20, 2015
Applicant:	Mölnlycke Health Care US, LLC 5550 Peachtree Parkway, Suite 500 Norcross, GA 30092 Registration number: 3004763499 Owner/Operator Number: 8030877
Official Correspondent:	Megan Bevill Regulatory Affairs Manager Tel: 470-375-0049 Fax: 678-245-7746 email: megan.bevill@molnlycke.com
Trade/Proprietary Names:	Biogel® PI Ultra Touch™ G Surgical Glove (ref. code 421) tested for use with chemotherapy agents Biogel® Skinsense® Surgical Glove (ref. code 314) tested for use with chemotherapy agents
Common Name:	Surgeon's Glove
Device Class:	Class I
Regulation Number:	21 CFR 878.4460
Product Code:	KGO [primary] LZC
Predicate Device Name(s):	Biogel® PI (polyisoprene) Surgical Gloves (K050184) Biogel ® Skinsense® (polychloroprene) Surgical Glove (K053102) Cardinal Health Esteem Polyisoprene Powder Free Surgical Glove (K110272) Cardinal Health (Allegance) Dermaprene Surgical Glove (K013302)

Description of Device:

The subject devices are disposable powder-free surgical gloves that are supplied sterile and are not made from natural rubber latex. They have been tested for use with chemotherapy agents. The

Biogel® PI UltraTouch™ G surgical gloves are made from synthetic polyisoprene material and the Biogel® SkinSense® surgical gloves are made from synthetic polychloroprene material. The gloves have been previously 510(k) cleared through K050184 and K053102 respectively.

Reason for 510(k) Submission:

The addition of the intended use claim 'Tested for use with Chemotherapy Drugs'.

Intended Use/Indication for Use:

The Biogel® PI UltraTouch™ G and the Biogel® Skinsense® surgical gloves are intended to be worn on the hands, usually in surgical settings, to provide barrier against potentially infections material, and other contaminants.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs:

Drug and Concentration	Breakthrough Detection Time in Minutes (0.01 µg/cm^2/ minutes)	
	Biogel® UltraTouch™ G	Biogel® Skinsense®
Bleomycin 15 mg/ml	>240	>240
Busulfan 6 mg/ml	>240	>240
Carmustine 3.3 mg/ml	12.1	60.2
Cisplatin 1.0 mg/ml	>240	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240	>240
Cytarabine 100 mg/ml	>240	>240
Dacarbazine (DTIC) 10 mg/ml	>240	>240
Doxorubicin Hydrochloride 2 mg/ml	>240	>240
Ellence 2 mg/ml	>240	>240
Etoposide (Toposar) 20 mg/ml	>240	>240
Fludarabine 25 mg/ml	>240	>240
Fluorouracil 50 mg/ml	>240	>240
Idarubicin 1 mg/ml	>240	>240
Ifosfamide 50 mg/ml	>240	>240
Mechlorethamine HCl 1 mg/ml	>240	>240
Melphalan 5 mg/ml	>240	>240
Methotrexate 25 mg/ml	>240	>240
Mitomycin C 0.5 mg/ml	>240	>240
Mitoxantrone 2 mg/ml	>240	>240
Paclitaxel (Taxol) 6 mg/ml	>240	>240
Paraplatin 10 mg/ml	>240	>240
Rituximab 10 mg/ml	>240	>240
Thiotepa 10 mg/ml	15.5	75.8
Trisenox 0.1 mg/ml	>240	>240

Vincristine Sulfate 1 mg/ml	>240	>240

Please note that Carmustine (3.3 mg/ml) and Thiotepa (10 mg/ml) have much lower permeation times compare to other chemotherapy drugs:

For Biogel® PI UltraTouch ™ G surgical glove:

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 12.1 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 15.5 minutes

For Biogel® Skinsense® surgical glove:

- Carmustine (BCNU) (3.3 mg/ml) has a minimum breakthrough time of 60.2 minutes.
- Thiotepa (10 mg/ml) has a minimum breakthrough time of 75.8 minutes.

Technological Characteristics and Performance:

The subject devices have been previously 510(k) cleared and have not undergone any modification in design or material. From a technological perspective, the subject devices remain substantially equivalent to the devices previously cleared though 510(k) K050184 and K053102. A tabular summary of features, technological characteristics and intended use is provided that includes a comparison between the subject devices and original devices cleared previously.

Summary of features and technological characteristics of the devices compared to the predicate devices				
	Subject Devices, 510(k) K140477	**K050184 and K053102**	**K110272**	**K013302**
Feature	Biogel® PI UltraTouch™ G tested for use with chemotherapy agents Biogel® Skinsense® tested for use with chemotherapy agents	Biogel® PI surgical gloves (K050184) Biogel® Skinsense® surgical gloves (K053102)	Sterile Polyisoprene Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs	Duraprene Sterile Synthetic Powder-Free Surgical Gloves Tested for Use with Chemotherapy Drugs Labeling Claim
Manufacturer	Mölnlycke Health Care	Mölnlycke Health Care	Cardinal Health	Allegiance Healthcare Corporation
Regulation Number	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460	21 CFR 878.4460
Common Name	Surgeon's Glove	Surgeon's Glove	Surgeon's Glove	Surgeon's Glove
Regulatory Classification	Class I	Class I	Class I	Class I
Product Code	KGO (primary product code) LZC (subsequent product code)	KGO (primary product code)	KGO LZC	KGO
Material Composition	*Biogel® PI UltraTouch™ G tested for use with chemotherapy agents* Synthetic Polyisoprene *Biogel® Skinsense® tested for use with chemotherapy agents* Synthetic Polychloroprene	*Biogel® PI* Synthetic Polyisoprene *Biogel® Skinsense®* Synthetic Polychloroprene	Synthetic polyisoprene	Neoprene (polychloroprene)
Design	Sterile, Single Use, Powder-free, Hand-specific, beaded cuff	Sterile, Single Use, Powder-free, Hand-specific, beaded cuff	Sterile, Single Use, Powder-free, Hand-specific, Independent Thumb, beaded cuff, lubricated	Sterile, Powder-free

Summary of features and technological characteristics of the devices compared to the predicate devices				
	Subject Devices, 510(k) K140477	**K050184 and K053102**	**K110272**	**K013302**
Intended Use	Surgeon's glove that is intended to be worn on the hands, usually in surgical setting, to provide barrier against potentially infectious material, and other contaminants. In addition, gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Gloves may be worn when administering chemotherapy.* *(*see note at bottom of table)*	Surgeon's glove that is intended to be worn on the hands, usually in surgical setting, to provide barrier against potentially infectious material, and other contaminants.	Powder-free surgeon's glove	Intended for use in environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.
Dimensions & Physical Properties	Meets ASTM D3577	Meets ASTM D3577	Meets ASTM D3577	Not specified in 510(k) summary
Freedom from Holes	AQL meets 21 CFR 800.20 & ASTM D3577 requirements	AQL meets 21 CFR 800.20 & ASTM D3577 requirements	AQL meets 21 CFR 800.20 & ASTM F3577 requirements	AQL exceeds 21 CFR 800.21 & ASTM D3577 requirements (AQL = 1.5)
Powder Residual	Meets requirements of $\leq$ 2.0 mg/glove for Powder-free designation per ASTM D3577	Meets requirements of $\leq$ 2.0 mg/glove for Powder-free designation per ASTM D3577	Meets requirements of $\leq$ 2.0 mg/glove for Powder-free designation per ASTM D3577	Meets requirements of $\leq$ 2.0 mg/glove for Powder-free designation per ASTM D6124-00
Biocompatibility				

Summary of features and technological characteristics of the devices compared to the predicate devices				
	Subject Devices, 510(k) K140477	**K050184 and K053102**	**K110272**	**K013302**
Primary Skin Irritation	Under the conditions of the study (per ISO 10993-10), the device is not an irritant	Meets ISO 10993-10 requirement	Gloves are non-irritating	Gloves show no intracutaneous reactivity
Sensitization (Guinea pig closed-patch)	Under the conditions of the study (per ISO 10993-10), the device is not a sensitizer	Meets ISO 10993-10 requirement	Gloves do not display any potential for sensitization	Gloves do not display any potential for irritation
Sterilization method	Gamma Radiation	Gamma Radiation	Not specified in 510(k) summary	Not specified in 510(k) summary
Sterility Assurance Level (SAL)	10^{-6} SAL	10^{-6} SAL	Not specified in 510(k) summary	Not specified in 510(k) summary

*note: The addition of the intended use claim 'Tested for use with chemotherapy drugs' is supported by permeation breakthrough times of chemotherapy agents. Minimum breakthrough times were determined for the subject devices using a wide range of chemotherapy drugs at the concentrations that are known to be common in standard clinical care. Comparisons are made between the subject devices and predicate devices that are currently 510(k) cleared and marketed for this specific use.

Chemotherapy Drug Permeation Testing:

Permeation testing was conducted to support the addition of the labeling claim: Tested for use with chemotherapy drugs. The gloves were tested according to ASTM D6978 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs. Minimum breakthrough times were determined for a wide range of chemotherapy drugs at the concentrations that are known to be common in standard clinical care. A tabular summary of the minimum breakthrough times is provided on the following next page. The summary provides a comparison of minimum breakthrough times between the subject devices and predicate devices that are currently 510(k) and marketed for use with Chemotherapy Drugs. These predicate devices include the Cardinal Health Esteem and Duraprene Surgical Gloves cleared through K110272 and K013302.

	Minimum breakthrough time in minutes (0.01 µg/cm2/minute)			
	Biogel® PI UltraTouch™ G	**Biogel® Skinsense®**	**Cardinal Esteem K110272**	**Cardinal Duraprene K013302**
Bleomycin 15 mg/ml	>240	>240	>240	not tested
Busulfan 6 mg/ml	>240	>240	>240	not tested
Carmustine 3.3 mg/ml	12.1	60.2	0.37	0.2
Cisplatin 1.0 gm/ml	>240	>240	>240	>240
Cyclophosphamide 20 mg/ml	>240	>240	>240	>240
Cytarabine 100 mg/ml	>240	>240	>240	not tested
Dacarbazine 10 mg/ml	>240	>240	>240	not tested
Doxorubicin Hydrochloride 2 mg/ml	>240	>240	>240	>240
Ellence 25 mg/ml	not tested	not tested	>240	not tested
Ellence 2 mg/ml	>240	>240	unavailable	not tested
Etoposide 20 mg/ml	>240	>240	>240	>240
Fludarabine 25 mg/ml	>240	>240	>240	not tested
Fluorouracil 50 mg/ml	>240	>240	>240	>240
Idarubicin 1 mg/ml	>240	>240	>240	not tested
Ifosfamide 50 mg/ml	>240	>240	>240	not tested
Mechlorethamine HCl 1 mg/ml	>240	>240	>240	not tested
Melphalan 5 mg/ml	>240	>240	>240	not tested
Methotrexate 25 mg/ml	>240	>240	>240	>240
Mitomycin 0.5 mg/ml	>240	>240	>240	not tested
Mitoxantrone 2 mg/ml	>240	>240	>240	not tested
Paclitaxel 6 mg/ml	>240	>240	>240	>240
Paraplatin 10 mg/ml	>240	>240	>240	not tested
Rituximab 10 mg/ml	>240	>240	>240	not tested
Thiotepa 10 mg/ml	15.5	75.8	0.44	82.2
Trisenox 0.1 mg/ml	>240	not tested	>240	not tested
Vincristine Sulfate 1 mg/ml	>240	>240	>240	>240

Conclusion:

The subject devices are substantially equivalent to the Biogel® Surgical Gloves previously 510(k) cleared (K050184 and K053102) with respect to design, technological characteristics and intended use. The subject devices are substantially equivalent to the Cardinal Health Power-free Surgical Gloves (K110272 and K013302) with respect to the addition of the chemotherapy use labeling and the permeation testing method and results for supporting such use. Clinical data was not required to demonstrate substantial equivalence. In conclusion, the subject Biogel® PI UltraTouch™ G and Biogel® Skinsense® surgical gloves are as safe, as effective, and perform as well as the predicate devices cleared under K050184 and K053102.